[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

PROSPECTIVE GRANT OF EXCLUSIVE EVALUATION OPTION LICENSE: Pre-clinical Evaluation of Human Therapeutics Utilizing Ubiquitin Based Fusion Proteins with Apoptosis Modifying Proteins such as BCL-X_L

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions covered under the scope of United States Patent No. 6,737,511 issued May 18, 2004 entitled "Receptor-mediated Uptake of an Extracellular BCL-x_L Fusion Protein Inhibits Apoptosis" (HHS Ref. No. E-073-1999/0-US-02; Inventors Richard Youle et al.) and International Patent Application No. PCT/US2012/032762 filed April 9, 2012 entitled "Ubiquitin Fusions for Improving the Efficacy of Cytosolic Acting Targeted Toxins" (HHS Ref. No. E-150-2011/0-PCT-02; Inventors Christopher Bachran et al.) to Medicenna Therapeutics, ("MEDICENNA") a Canada based company. The

patent rights in this invention have been assigned to the government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to the pre-clinical evaluation of lead therapeutic candidates for the development of human therapeutics within the field of cancer and neurological diseases. Upon expiration or termination of the exclusive evaluation option license, MEDICENNA will have the right to execute an exclusive patent commercialization license which will supersede and replace the exclusive evaluation option license with no broader territory than granted in the exclusive evaluation option license and the field of use will be commensurate with the commercial development plan at the time of conversion.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 402-0220; E-mail: chatterjeesa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The technologies covered under the present inventions relate to 1) apoptosis-modifying fusion proteins with at least two domains, one of which targets the fusion proteins to a target cell, and another of which modifies an apoptotic response of the target cell. For example, fusing various cell-binding domains to Bcl-X_L and Bad allows targeting to specific subsets of cells *in vivo*, permitting treatment and/or prevention of cell-death related consequences of various diseases and injuries. This technology could be used to minimize or prevent apoptotic damage that can be caused by neurodegenerative disorders, e.g., Alzheimer's disease, Huntington's disease or spinal-muscular atrophy, stroke episodes or transient ischemic neuronal injury, e.g., spinal cord injuries. Additionally, apoptotic-enhancing fusion proteins of the current invention could be used to inhibit cell growth, e.g., uncontrolled cellular proliferation and 2) a platform technology using ubiquitin to improve the delivery and efficacy of cytosolic targeted toxins. This invention describes generation of fusion proteins via the introduction of the protein ubiquitin, a small protein in eukaryotic cells that plays a role in protein recycling, in between a targeting moiety and a catalytic moiety. Ubiquitin contains a cleavable motif at its C-terminus, which can help in the decoupling of the two moieties. Decoupling of the two moieties would increase the cytotoxicity of the treatment, since the catalytic domain of a Targeted Toxin (TT) remains longer in the cytosol. This method of generating fusion proteins would be highly useful for all TT and immunotoxins that access the cytosol to either affect cytosolic targets or traffic to further sites of action.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on October 1, 2011and will comply with the terms and

conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive evaluation option license, and a subsequent exclusive patent commercialization license, may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Any additional, properly filed, and complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

October 23, 2012
Date

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Richard U. Rodriguez,
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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